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IN THE

Supreme Court of the United States

CHARLES R. RIEGEL, *et ux.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE STATES OF NEW YORK, ARIZONA, ARKANSAS, CONNECTICUT, DELAWARE, FLORIDA, HAWAII, IDAHO, ILLINOIS, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEVADA, NEW MEXICO, NORTH DAKOTA, OHIO, OREGON, SOUTH CAROLINA, TENNESSEE, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING, AND THE DISTRICT OF COLUMBIA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

ANDREW M. CUOMO
Attorney General of the State of New York
BARBARA D. UNDERWOOD*
Solicitor General
MICHELLE ARONOWITZ
Deputy Solicitor General
RICHARD DEARING
CECELIA CHANG
Assistant Solicitors General
120 Broadway, 25th Floor
New York, NY 10271
(212) 416-8020

* *Counsel of Record*

Attorneys for Amici Curiae

(Additional Counsel Listed on Signature Pages)

QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

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INTEREST OF THE AMICI

In our federal system, the amici States have historically taken the leading role in matters of health and safety.[1] In that arena, state product liability law has long served to provide incentives for product manufacturers to make their products safe and effective, to compensate individual consumers injured by unsafe products, and to spread the risks of product defects across large segments of society by requiring firms to internalize damages from injuries or deaths caused by their products as costs of doing business.

By enacting the Medical Device Amendments ("MDA") in 1976, Congress for the first time vested the Food and Drug Administration ("FDA") with new and broad authority to regulate medical devices intended for human use. This included the responsibility of pre-clearing the newest and highest-risk medical devices before they were permitted to be brought to market. This premarket approval ("PMA") process entailing *ex ante* review of proposed new medical devices no doubt prevents many unsafe devices from ever being sold, but it is no substitute for *ex post* adjudication in product liability suits based on individuals' actual experiences with a device under real-world conditions. The PMA process and state tort law thus work together to help ensure the safety of medical devices.

The lower court's holding that the PMA process broadly displaces state product liability suits involving approved devices, if not reversed by this Court, would imperil the health and safety of amici States' consumers. It would also

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1. Amicus the District of Columbia is not a State. However, Congress has delegated broad police powers to the District to enable it to protect the health and safety of its residents. *See, e.g., District of Columbia v. John R. Thompson Co.*, 346 U.S. 100, 109 (1953). The District of Columbia, therefore, also has a strong interest in the preemption issue before the Court.

unnecessarily and improvidently nullify state law where it complements, and does not conflict with, the goals of the federal statute.

ARGUMENT

I. The Text of the MDA and Implementing Regulations Demonstrate that Congress Intended to Allow Room for State Law to Operate Where It Furthers the Act's Fundamental Safety Objectives.

As this Court held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), analysis of the scope of the MDA's preemption clause, 21 U.S.C. § 360k(a), is guided by two overarching principles. First, the purpose of Congress is the "ultimate touch-stone" in all preemption cases, requiring consideration of the statutory text and structure, as well as "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Lohr*, 518 U.S. at 485-86. Second, respect for the States' role as "independent sovereigns in our federal system" gives rise to a presumption against preemption in fields that the states have historically occupied. *Id.* at 485. In those areas, the congressional purpose to preempt must be "clear and manifest" for the States' traditional powers to be found superseded. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005). Health and safety are just such fields of traditional state power, *see Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985), and were Congress's motivating concerns in enacting the MDA.

The MDA was enacted in 1976 to enhance the safety and effectiveness of medical devices by providing increased statutory authority for the FDA to regulate them. *See, e.g.*, S. Rep. 94-33, at 1-2 (1976), *reprinted in* 1976 U.S.C.C.A.N.

1070, 1070-71.[2] The Act was passed against the backdrop of numerous reported deaths and serious injuries caused by newly developed medical devices, such as the Dalkon Shield intrauterine device, pacemakers, and artificial heart valves. S. Rep. 94-33, at 1-2, 6-7, *reprinted in* 1976 U.S.C.C.A.N. at 1070-1071, 1076. It was also enacted in the context of a long history of tort litigation under state law to protect individual consumers from dangerous and defective products. *See, e.g., MacPherson v. Buick Motor Co.*, 217 N.Y. 382 (1916) (Cardozo, J.) (developing theory of strict product liability); *cf. Lohr*, 518 U.S. at 485 (acknowledging "the historic primacy of state regulation of matters of health and safety"). That history "adds force to the basic presumption against pre-emption." *Bates*, 544 U.S. at 449.

In this case, the issue is whether the FDA's grant of premarket approval to a new medical device preempts product liability claims under state law. As explained in detail below, neither the text nor the legislative history of the MDA indicates that Congress intended the PMA process to have such broad preemptive effect. The MDA is a safety statute, not a tort reform statute, and the Act makes clear that there is ample room for state law to serve a complementary role in ensuring the safety of medical devices.

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2. Although some comments in the legislative history reflect a subsidiary concern about hampering medical innovation, those comments "were related more to the risk of *additional* federal and state regulation rather than the danger of pre-existing duties under common law." *Lohr*, 518 U.S. at 490 (plurality opinion). As *Lohr* noted, the legislative history contains no references to fears about the impact of state "product liability actions" on "the development of medical devices." *Id.* Any congressional intention to avoid overregulation "was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision." *Id.* "[F]urthermore, any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices." *Id.* at 490-91.

The MDA contains several distinct provisions that demonstrate the complementary roles of state and federal regulation in this area. First, the express-preemption clause in § 360k(a) is narrowly drawn, displacing state medical-device regulation only where it conflicts with a particular federal interest, as embodied in a specific federal counterpart regulation. Second, in § 360k(b), Congress authorized the FDA to grant an exemption from preemption to state laws in defined circumstances — including where state law is more stringent, and thus more protective of patients and consumers, than federal regulation. Third, the Act includes a saving clause, § 360h(d), which expressly provides that although federal remedies may sometimes provide a limited benefit to individual patients or consumers where devices prove defective, those remedies are not meant to relieve a manufacturer from existing liability for damages under state law.

Where the FDA grants a PMA to permit a new medical device to be brought to market, state tort suits maintain an important place in monitoring the safety of the device after it is marketed, based on the device's actual use under real-world conditions. Indeed, this Court has repeatedly recognized that state common-law claims can play an important, complementary role in furthering the goals of federal safety legislation. *See, e.g., Bates*, 544 U.S. at 451 (explaining that state tort suits can serve as a "catalyst" in exposing new hazards and bringing new information to attention of federal agencies); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("It would have been perfectly rational for Congress not to pre-empt common-law claims, which — unlike most administrative and legislative regulations — necessarily perform an important remedial role in compensating accident victims.").

It is simply implausible that Congress, when it charged the FDA in 1976 to begin conducting *ex ante* review of new medical devices based on clinical data and other information

provided by the device manufacturer, would have meant to supersede all of state tort law in the area of device safety. Even more far-fetched is the notion that Congress would have displaced state common law so broadly without comment, and with no workable avenue for the FDA to grant exemptions from preemption when general common-law duties promote the underlying goal of ensuring device safety, as the agency can do when state medical-device statutes or regulations would otherwise be preempted.

Congress's silence as to whether common-law remedies are preempted by the PMA process "takes on added significance in light of Congress' failure to provide any federal remedy" for injuries, including deaths, caused by unsafe medical devices, the very danger that prompted the MDA's enactment. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Bates*, 544 U.S. at 449 (emphasizing that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"). Like many other federal statutory schemes in the area of health and safety,[3] the MDA operates in conjunction with, and without preempting, state common-law remedies, which offer additional or parallel protection for consumers.

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3. *See, e.g., Bates*, 544 U.S. at 443-452 (Federal Insecticide, Fungicide and Rodenticide Act [FIFRA] does not preempt state common-law or statutory deceptive practices claims against pesticide and herbicide manufacturers); *Sprietsma*, 537 U.S. at 64-70 (Federal Boat Safety Act did not preempt common law tort claims against outboard motor manufacturer for failing to install a propeller guard).

A. The Limited Scope of Section 360k, and the Section's Exemption Mechanism, Show that Congress Viewed Federal Device Regulation and Continued Application of State Law as Largely Compatible.

By its terms, the MDA's express-preemption clause, 21 U.S.C. § 360k(a), does not displace all state law that applies to medical devices or device manufacturers.[4] The clause is limited, and preempts only a state "requirement" established "with respect to" a medical device, and only when that requirement is "different from, or in addition to" a federal "requirement" "applicable to" the same device. The statutory language, together with the FDA regulations discussed below, "suggest that [the preemption clause's] focus is device-specific enactments of positive law by legislative or administrative bodies," not general common-law duties. *Lohr*, 518 U.S. at 489 (plurality opinion).

Moreover, pr[illegible]mption occurs only where there is a close correspondence in the subject matter and nature of the federal and state requirements. As this Court held in *Lohr*, § 360k(a) requires a carefully targeted "comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope" of the statute. *Id.* at 500. The

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4. Section 360k(a) provides as follows:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this Act [21 U.S.C. §§ 301 et seq.] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act. . . .

inquiry under § 360k(a) is both specific and narrow: preemption "occur[s] only where a particular state requirement threatens to interfere with a specific federal interest." *Id.*

That federal and state law are to a large extent complementary here, not at odds, is further shown by the FDA's preemption regulation, 21 C.F.R. § 808.1, which "substantially informed" this Court's analysis in *Lohr*. 518 U.S. at 495. The FDA played a significant role in the MDA's development, and the implementing regulations that the agency formally promulgated soon after the Act's passage provide critical insight about the intended scope of preemption. Like the statutory provisions discussed above, 21 C.F.R. § 808.1 demonstrates that much of state law was meant to be preserved.

Specifically, § 808.1(d) provides that state device requirements are preempted "only" when the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to a particular device." And even where a device-specific federal requirement has been established, the regulation envisions that many kinds of state requirements will remain in force. For instance, there is no preemption of "State or local requirements of general applicability that relate only incidentally to medical devices." Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications, 42 Fed. Reg. 30383, 30384 (June 14, 1977). In other words, a state requirement survives where its purpose "relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1).[5]

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5. This regulatory provision demonstrates that the FDA agrees that many state consumer-protection statutes are not preempted, such as New York Executive Law § 63(12), which permits the Attorney General of New York to investigate persistent fraud and illegality in the conduct of business within the State and to seek judicial redress where appropriate.

As specific examples of non-preempted general state requirements, the regulation identifies general electrical codes and the implied warranty of fitness under the Uniform Commercial Code ("U.C.C."). *Id.* The reference to U.C.C. implied warranties is most revealing, since that is a statutory source of product liability closely analogous to common-law negligence and strict liability, and indeed is frequently pleaded in conjunction with common-law theories. *See, e.g., Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 255-56 (1995) (explaining historical development of U.C.C. warranty and strict liability claims and noting the "high degree of overlap" and essential congruence of both claims). Moreover, implied warranty claims, like common-law theories, require the application of a general liability standard to the facts and circumstances of a particular case. The regulatory statement that implied warranty claims survive therefore provides strong support for the conclusion that common-law claims should survive also.[6]

The FDA's preemption regulation also provides that § 360k(a) does not "preempt State or local requirements respecting general enforcement," such as inspection requirements for device-manufacturing facilities, or registration and licensing schemes for device manufacturers. *Id.* § 808.1(d)(6)(I). The regulation thus confirms that the MDA in large part embraces, not displaces, state law that touches on the safety and effectiveness of medical devices.

Further dispelling any notion that Congress viewed federal device regulation and the continued application of

6. The FDA's 1978 preemption regulation presumably singled out as not preempted statutes imposing general standards of care, like the U.C.C., but did not identify state common-law doctrines imposing similar general standards, because the regulation focused on § 360k(a)'s preemptive effect on state positive enactments, which were the statute's main target, not common-law duties.

state law as broadly incompatible, § 360k(b) of the MDA authorizes the FDA to exempt state requirements from preemption upon application by "a State or a political subdivision thereof," where either (1) the state requirement is "more stringent" than a counterpart federal requirement under the MDA, or (2) the state requirement is "required by compelling local conditions" and compliance would not cause the device to be in violation of any federal requirement.

The MDA's legislative history demonstrates that the exemption mechanism was no afterthought, but an integral element of Congress's design, reflecting its recognition that in "some situations . . . regulation of devices by States and localities would constitute a useful supplement to Federal regulation." H.R. Rep. No. 94-853, at 45 (1976). The House Committee Report on the bill described a California medical-device statute that was "the most comprehensive" then in existence "as an example of [the sort of state] requirements that [the FDA] should authorize to be continued" if otherwise preempted under § 360k(a). H.R. Rep. No. 94-853, at 45;[7] *see also* 122 Cong. Rec. 5,859 (1976) (remarks of Rep. Waxman) (noting that exemption mechanism would "permit California's progressive program to continue in effect in that State").[8]

As a structural matter, Congress's inclusion of the exemption mechanism for more stringent state regulation counsels for restraint in finding common-law duties to be preempted. Because, as explained below, the exemption process is unavailable as a practical matter for common-law claims,

7. Among other things, the California statute required premarket approval for new medical devices, established good manufacturing practices for medical devices, and authorized inspection of device-manufacturing facilities. *See* H.R. Rep. No. 94-853, at 45.

8. The FDA has granted numerous exemptions to state statutes and regulations that govern the dispensing of hearing aids, *see*, 21 C.F.R. §§ 808.53, 808.57-.101, one of the relatively few areas in which the FDA has promulgated specific federal regulations, *see id.* §§ 801.420-.421.

holding common-law claims such as the Riegels' preempted would give rise to the anomaly that preemption would be broader and more definitive as to common-law tort claims than as to state positive-law regulation, even though the presumption against preemption is especially strong as to longstanding tort causes of action. *See Bates*, 544 U.S. at 449.

The exemption process is virtually unavailable for common-law claims for several reasons. The FDA's regulation makes clear that in ruling on an application for exemption, the agency must consider state law as applied in order to determine whether state law is more stringent than federal law, and whether it is responsive to local conditions. *See* 21 C.F.R. § 808.20(c)(1). Yet it is extremely difficult for a particular State to know in the abstract whether and to what extent state common law is more stringent than federal law with respect to a particular device, or whether its common-law rules are compelled by distinctive local conditions.

Nor would a State be in a position to apply for an exemption from preemption *after* a specific jury verdict on a plaintiff's claim against a particular device, since the preemption defense will prevent such claims from going to the jury in the first place. In any event, since only States or political subdivisions, and not private individuals, may apply for an exemption, a designated government official would have to review every pending or contemplated private tort action to decide whether to seek an exemption.

Thus, under respondent's interpretation of § 360k, common-law duties would be preempted without possibility of exemption, and hence even more decisively than state statutory or regulatory provisions. That result is particularly incongruous in light of the legislative and regulatory history demonstrating clearly that § 360k was targeted at state positive-law enactments rather than common-law duties. For example, the House committee report focused on situations, like California's medical-device statute, where "States ha[d] established their own programs" for

medical-device regulation in the absence of effective federal regulation. H.R. Rep. No. 94-853, at 45. Similarly, an FDA publication released shortly after the MDA's passage envisioned state or local positive enactments as the only possible candidates for preemption: "When *State or local device laws and regulations* are preempted, the State may petition FDA under section 521(b) for an exemption from the 521(a) preemption." U.S. Dep't of Health, Educ., and Welfare, Pub. Health Serv., Food & Drug Admin., Bureau of Med. Devices, *Everything you always wanted to know about the medical device amendments . . . and weren't afraid to ask* 35 (Oct. 1977) (emphasis added).

B. The MDA's Saving Clause Shows that Congress Took Care to Preserve Manufacturers' Liability For Damages Under State Law Where Approved Devices Prove Unsafe and Cause Injury.

Not only the text and structure of § 360k but also the savings clause of the MDA, 21 U.S.C. § 360h(d), shows that Congress contemplated that state tort law would complement federal device regulation and would not be displaced by it. Section 360h generally describes the FDA's authority to require a device manufacturer to take certain steps — such as notifying the public, repairing or replacing a device, or refunding the purchase price — when the agency concludes that a device already on the market "presents an unreasonable risk of substantial harm to the public health." 21 U.S.C. § 360h(b).

Section 360h is the sole section of the MDA that provides remedies that directly benefit individual patients or consumers. And in that area, Congress took pains to include a saving clause clarifying that the statutory remedies were in addition to, not in lieu of, existing remedies under state law. Accordingly, subsection (d) provides that "[c]ompliance with

an [FDA] order [under § 360h] shall not relieve any person from liability under Federal or State law." This savings clause clearly contemplates tort liability, as shown by its provision that "[i]n awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account."

Accordingly, the "only congressional discussion" about the relationship between the MDA and state tort remedies "indicates that Congress assumed that such remedies would be available." *Silkwood*, 464 U.S. at 251 (addressing the federal Atomic Energy Act). The inclusion of the saving clause and its offset provision demonstrates that Congress did not intend that device regulation under the MDA would supplant traditional state tort law.

II. The MDA Does Not Evince a Clear and Manifest Congressional Purpose that the Federal Premarket Approval Process Should Replace Postmarket State Product Liability Suits.

The specific preemption issue here is whether the FDA's grant of a PMA to Medtronic's Evergreen Balloon Catheter preempts the Riegels' product liability claims related to the design and labeling of the device. With the enactment of the MDA in 1976, Congress for the first time provided for the FDA to conduct premarket review of medical devices. The statute reserves the PMA process for devices that are most novel and present the greatest potential risks to human safety. *See* 21 U.S.C. § 360c(a)(1)(C). It is implausible that Congress would have intended this untested regime of *ex ante* FDA marketing approval of high-risk medical devices (with no provision of its own to remedy personal injury from marketed devices) to supplant the longstanding role played by the tort system in addressing device safety based on patient experiences after a device's actual use on the market. That is

particularly true since the MDA's passage was spurred by the occurrence of numerous deaths and serious injuries caused by new and technologically sophisticated medical devices in the 1960s and early 1970s. Certainly, in the *ex ante* PMA provisions there is no clear and manifest congressional purpose to preempt postmarketing personal injury claims, as is required to overcome the presumption against preemption. Accordingly, and as explained further below, the PMA process leaves ample room for state product liability suits to continue to protect and compensate medical-device users when approved devices prove to be unreasonably dangerous and cause injury.

1. In order to determine whether § 360k(a) preempts state common law, *Lohr* teaches that it is necessary to identify the specific federal "requirement" claimed to have preemptive effect, and then conduct a "careful comparison" between that federal requirement and the state law in question to determine whether the state law "fall[s] within the intended pre-emptive scope [of the federal requirement]." 518 U.S. at 500. For certain medical devices the MDA indisputably establishes a federal "requirement" that the manufacturer obtain the FDA's approval before marketing the device. That federal PMA requirement has preemptive effect on its state counterparts — i.e., state statutes or regulations that likewise purport to establish a threshold process for obtaining permission to market the device. But the federal PMA requirement does not preempt product liability suits alleging that an approved device was shown to be unreasonably dangerous by events that occurred after the device was sold to consumers or used in treating patients.

There is little doubt that the federal PMA requirement preempts "different or additional State and local premarket approval requirements," absent the grant of an exemption from preemption by the FDA. Exemptions from Federal

Preemption of State and Local Device Requirements: Procedures for Consideration of Applications, 43 Fed. Reg. 18661, 18664 (1978). For example, a state statute or regulation requiring pre-clearance of new devices by a state agency, such as the California medical-device statute discussed above, establishes a requirement "in addition to, or different from" the MDA's premarket approval requirement, and without an exemption is preempted under § 360k(a). Similarly, if a state statute or regulation purported to authorize marketing of a new device without FDA premarket approval, such a provision would be preempted as in direct conflict with federal law.

A grant of a PMA does not, however, establish comprehensive federal "requirements" as to the specifics of a device's design and labeling, thereby preempting all defective-design and failure-to-warn claims alleging that the approved device is unreasonably dangerous. The FDA does not prescribe mandatory standards for a particular device merely by approving the PMA application prepared by the device manufacturer, and does not "require" the device to take any particular form. Moreover, the FDA's grant of a PMA does not explicitly or implicitly reject *other* putative devices with new or different features. FDA approval in no way signifies that federal law disfavors changes to the device's design or labeling. It merely means that the FDA has determined that the device as approved meets the minimum threshold of safety and effectiveness necessary to permit it to be brought to market.[9]

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9. Until recently the FDA itself shared this view as to the import of a PMA grant. *See* Brief for United States as Amicus Curiae in Opposition to Certiorari at 14, *Smiths Indus. Med. Sys., Inc. v. Kernats* (No. 96-1405) (PMA grant signifies that device meets "the applicable federal minimum standards for use and marketing"); *id.* at 15 (general criteria for premarketing approval "establish minimum standards that do not displace state law standards of care or common law duties respecting the medical device").

2. For similar reasons, the prohibition on changing an approved device or its label without supplemental FDA approval, *see* 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(a), is not tantamount to a federal "requirement" that the device never be improved from its approved specifications. A device manufacturer is not categorically prohibited from changing a previously approved device; rather, the ability to make a change is merely conditioned on FDA approval. Certain kinds of labeling or manufacturing changes that "enhance[] the safety of the device" are presumptively allowed prior to obtaining such approval. 21 C.F.R. § 814.39(d).[10] The existence of a precondition to changing the device is not tantamount to a "requirement" that the device adhere to previously approved specifications, because the manufacturer is free to change the device upon seeking and obtaining approval through a supplemental PMA application. And since the decision whether to seek such approval in the first place is entirely within the manufacturer's control, it would create perverse incentives against device improvement to allow a manufacturer to rest on its initial FDA approval in any future state-law tort suit, on the theory that federal law "required" the manufacturer to maintain the approved design and labeling.

The error of characterizing a grant of a PMA as establishing specific design and labeling requirements is shown by the facts of a recent case in Wisconsin state court. *See Blunt v. Medtronic, Inc.*, No. 2006AP1506, 2007 Wisc. App. LEXIS 667 (Wis. App.

10. Permitted modifications include (1) adding or strengthening a contraindication or warning on the label; (2) adding or strengthening an instruction intended to enhance the safe use of the device; or (3) deleting misleading, false, or unsupported indications. 21 C.F.R. § 814.39(d)(2). The gravamen of the Riegels' failure-to-warn claim is that Medtronic should have strengthened an instruction regarding the inflation limits of its Evergreen Balloon Catheter, a change that would appear to fit the description of those permitted without prior FDA approval.

July 31, 2007). That case concerned a device — an implantable defibrillator — for which Medtronic obtained premarket approval in 2002. Medtronic obtained supplemental approval for a modification of the device a year later. *Id.* at *1-2. However, Medtronic continued to market the device in its original form to clear accumulated inventory. *Id.* at *25 (Fine, J., dissenting). The plaintiff was injured by the original device in 2004, and claimed that the design was defective and the modification was necessary to satisfy the standard of care under state law. *Id.* at *22-23. Medtronic took the position that the plaintiff's claims were preempted, and the Wisconsin state court agreed. *Id.* at *24. That finding of preemption, under *Lohr*, implies that the initial grant of a PMA established a federal requirement to use the original design. But plainly the PMA imposed no such requirement, because at the time of the injury the FDA had also approved the modified design.

If a manufacturer has submitted a supplemental application to make a particular design or labeling change, and the FDA has rejected that application, it might make sense to find preemption of a product liability suit claiming that the specific change was necessary to make the device reasonably safe. But when, as here, a manufacturer has not submitted an application to change the device in any relevant respect, there is no basis for concluding that federal law "requires" the device to take its original form and conflicts with a plaintiff's assertion that the device should have been designed or labeled differently.

3. While the PMA process is more demanding than the premarket notification process considered in *Lohr*, that is not sufficient reason to give broad preemptive effect to the grant of a PMA. *Ex ante* review of a medical device prior to marketing is a predictive process with limitations that make it ill-suited to replace *ex post* adjudication based on the device's actual use in the real world. Given the context in

which the MDA was enacted, the PMA process is best understood as an additional layer of protection to the public that helps prevent some unsafe devices from reaching the market, not a conclusive guarantee of product safety and effectiveness that should discourage further product development or preclude future product liability suits.

Indeed, in 1986, a decade after the MDA's passage, the Director of the FDA's Center for Devices and Radiological Health (which processes PMA applications) acknowledged that the FDA's "system of approving devices isn't perfect, and that unexpected problems [with approved devices] do arise." U.S. Dep't of Health and Human Serv., Public Health Serv., Food & Drug Admin., *The Medical Device Amendments: 10 Years After* 1 (1986). Years later, a House subcommittee report identified "a number of cases in which the FDA [had] approved devices that proved unsafe in use." House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 93rd Cong., *Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health* 1-3 (Comm. Print. 103-N 1993); *see also id.* at 21-24, 31-33.

A principal shortcoming of the PMA process is that the data supporting a PMA application are compiled by the device manufacturer and are often unreliable. In 1993, an FDA committee found flaws in the design, conduct, and analysis of the clinical studies used to support PMA applications that were "sufficiently serious to impede the agency's ability to make the necessary judgments about [device] safety and effectiveness." Food & Drug Admin., Comm. for Clinical Review, *Final Report: Based on a Review of Selected Medical Device Applications* 1-4 (March 1993), *reprinted in Less Than the Sum of Its Parts* at 99-102; *see also The Medical Device Amendments: 10 Years After*, at 1 ("One of the main

reasons [problems arise after approval] is that the data upon which we base our safety and effectiveness decisions isn't perfect."). Similarly, in 1996, the Inspector General of the Department of Health and Human Services reported "serious deficiencies . . . in the clinical data submitted as part of pre-market applications," and further observed that "[w]hen such deficiencies go undetected, medical device approvals may pose health risks for consumers." Office of the Inspector General, U.S. Dep't of Health and Human Services, *Review of the Food and Drug Administration's Processes to Review Medical Device Submissions under the Pre-Market Approval and Investigational Device Exception Programs* 2 (March 1996). The report concluded that changes to processes for auditing data supplied by PMA applicants were necessary to "help prevent unsafe or ineffective critical devices from endangering the public." *Id.* at 10. Moreover, "limitations [are] inherent" in even the best-designed and most reliable clinical studies conducted by manufacturers, since those studies by their nature cannot "duplicat[e] all aspects and hazards of everyday use." *Less than the Sum of Its Parts* at 59.[11]

The MDA's legislative history identifies other limitations in the PMA process that undermine any claim that Congress intended it to replace case-by-case adjudication in tort lawsuits. For example, in some cases, "[a] device may . . .

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11. In a 2004 amicus filing, the United States argued that premarket approval of a particular device is most analogous to an agency adjudication, rather than a rule-making. Brief for United States as Amicus Curiae at 23-24, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). The effect of an agency adjudication in a future lawsuit usually falls under the rubric of preclusion, not preemption. Under ordinary preclusion principles, the FDA's determination in the essentially one-sided PMA process would receive no preclusive effect because the Riegels lacked an adequate opportunity to litigate the issue before the agency. *See U.S. v. Utah Constr. & Mining Co.*, 384 U.S. 394, 422 (1966).

[be] approved based upon an evaluation of the safety and efficacy of certain of its aspects," but it may later "be discovered that other aspects of the product" make it unsafe. H.R. Rep. No. 94-853, at 32. In other situations, technological changes occurring after FDA approval can render unreasonable a safety risk that was reasonable at the time of the FDA's consideration. *Cf.* H.R. Rep. 94-853, at 23 ("[T]here are instances in which a device presented a reasonable risk according to the state of the art at the time of its manufacture which becomes unreasonable due to a change in technology.").

To be sure, the PMA process does not necessarily represent the FDA's only point of contact with an approved device. Largely as a result of amendments passed in the 1990s, beginning with the Safe Medical Devices Act of 1990, Pub. L. 101-629, 104 Stat. 4511, the MDA also addresses postmarket controls of devices as to which the FDA has granted approval, including sections that provide for the FDA to receive reports of injuries caused by a device, require manufacturers to conduct "postmarket surveillance" with respect to devices in some instances, and give the FDA authority to order the recall of a device that has proven unsafe, as well as other similar remedies. *See* 21 U.S.C. §§ 360h, 360i, 360l. But these mechanisms hardly make up for the limitations of the PMA process or eliminate the need for the continuing incentives provided by the threat of tort liability for the marketing of unreasonably dangerous devices. Indeed, a 1997 GAO report found that even when problems with a device are disclosed to the FDA in the postmarketing surveillance process, the agency "does not systematically act to ensure that the reported problems receive prompt attention and appropriate resolution." U.S. General Accounting Office, *Medical Device Regulation: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* 2 (1997).

4. A ruling that a grant of a PMA does not by itself preempt product liability suits would not render the preemption clause in § 360k(a) a nullity for those devices subject to PMA. As discussed *supra* at 13-14, the federal PMA requirement preempts counterpart state or local market pre-clearance requirements absent the grant of an exemption from preemption. Moreover, the FDA may promulgate regulations establishing specific design or labeling standards for a device or type of devices that have preemptive effect on counterpart state device requirements.

In particular, if the FDA concludes that aspects of the technology underlying a particular device or type of devices is sufficiently mature and that there is an adequate and reliable information base, the agency may promulgate device-specific performance standards through notice-and-comment procedures set out in the MDA. *See* 21 C.F.R. § 861.1(b)(3); S. Rep. No. 94-33, at 13 ("The Committee wishes to make it clear that standards and premarket approval mechanisms are not mutually exclusive."), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1082. If and when it does so, the FDA should of course give careful consideration to the potential consequences of proposed regulations regarding displacement of state law. *See* Executive Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999) (requiring particular sensitivity to federalism concerns in agency rule-makings with preemptive consequences).

Such mandatory prescriptions by regulation, unlike the mere grant of a PMA, may constitute specific federal requirements that preempt different or additional state device standards.[12]

12. The preemptive effect of such a federal regulation would most naturally extend to device-specific state statutes or regulations establishing different or additional requirements for the device. Determining whether the federal regulation would preempt state common-law duties in any particular case would require the "careful comparison" between federal and state law that § 360k(a) demands. *See Lohr*, 518 U.S. at 500, *see also id.* at 502 (holding that the generality of common-law duties usually disqualifies them from being requirements "with respect to" a specific device within the meaning of § 360k(a)).

For example, in 1978, the FDA promulgated regulations establishing labeling requirements and conditions for sale for hearing aids and expressly stated that those regulations preempted state hearing-aid requirements addressing labeling and conditions for sale, unless they were granted exemptions from preemption. *See* 21 C.F.R. §§ 801.420, 801.421; Exemptions from Federal Preemption of State and Local Device Requirements: Procedures for Consideration of Applications, 43 Fed. Reg. 18661, 18662 (May 2, 1978). But even there, the FDA stressed the need for strict congruence in subject matter between the federal and state requirements for preemption to occur, observing that "only [state] requirements relating to [hearing-aid] labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution." *Id.*

All of these reasons show why a grant of a PMA should not preempt state product liability suits, which fulfill a vital and complementary role alongside the PMA process. Such suits provide needed protection and compensation for patients and consumers injured by devices based on actual use in real-world conditions. The *ex ante* PMA procedure, while likely effective in preventing many unsafe devices from reaching the market, cannot ensure the safety of those devices that *are* marketed. Additionally, the threat of product liability suits creates continuing incentives for product manufacturers to improve the safety of their device after receiving a PMA. *See Bates*, 544 U.S. at 451 ("'[T]he specter of damage actions may provide manufacturers with added dynamic incentives to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.'") (quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)).

III. The FDA's Newly Minted Position on the Preemptive Effect of Premarket Approval Is Entitled to No Weight.

For several reasons, no weight should be afforded to the United States' current litigating position as to the preemptive effect of a PMA, first announced in a 2004 amicus brief, which asserts that a grant of FDA approval represents both a floor and a ceiling as to the safety and effectiveness of an approved device, and displaces all state product liability claims except where it is alleged that the manufacturer failed to adhere to the specifications in his approved application. Brief for United States as Amicus Curiae at 13-31, *Horn*, 376 F.3d 163.

First, this Court generally has not granted deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), to an agency's position as to the preemptive scope of a federal statute. *See Lohr*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference."); *cf. Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 743-44 (1996) (assuming without deciding that the question of a statute's preemptive effect "must always be decided *de novo* by the courts"). There are good reasons not to afford *Chevron* deference in this area. Not only does preemption analysis require application of complex legal doctrines, a task at which the courts are most expert, but preemption of state law also raises sensitive questions of federalism, which agencies are ill-equipped to resolve. Perhaps for that reason, this Court recently relied on its own interpretation of a federal statute's preemptive effect, rather than relying on deference to an agency's similar position or even deciding what degree of deference might be due that position. *See Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 & n.13 (2007). As Justice Stevens observed

in dissent in that case, "when an agency purports to decide the scope of federal preemption, a healthy respect for state sovereignty calls for something less than *Chevron* deference." *Id.* at 1584 & n.25 (Stevens, J., dissenting).

To be sure, this Court has on occasion, including in *Lohr* itself, looked to an agency's views to inform the application of preemption doctrine to a particular issue, especially when the analysis implicates technical matters. *See* 518 U.S. at 495-96; *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (giving "some weight" to agency opinion on conflict preemption). But it has not done so where following the agency's position would effectively nullify the strong presumption against preemption. In *Lohr*, the Court consulted the FDA's regulation, 21 C.F.R. § 808.1, for guidance in identifying a narrow construction of § 360k(a) that was fully consonant with the presumption against preemption. 518 U.S. at 495-96. And in *Geier*, the Court did not hold the presumption against preemption to be applicable; therefore, giving weight to the agency's position favoring preemption did not require overruling the presumption.

As this Court ruled in *Bates*, the presumption against preemption, where it applies, compels a court to adopt the construction of an express preemption clause that disfavors preemption of state law, even where the United States, on behalf of an agency, files a brief asserting a different view. 544 U.S. at 449; *see also id.* at 436-37 & n.7. The presumption requires a clear indication of congressional purpose for preemption to occur, and an administrative agency cannot supply the required clear statement where Congress has not. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 n.9 (2d Cir. 2006) ("[A]n agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption."). This Court has embraced a similar argument

in the context of the constitutional-avoidance doctrine, which is an analogous clear-statement principle that trumps even *Chevron* deference and requires construction of an ambiguous statute to avoid constitutional questions, notwithstanding a contrary agency interpretation. *See Solid Waste Agency of N. Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172 (2001); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 574-577 (1988).

A second and independent reason for giving little or no weight to the FDA's current view of preemption is that it was developed and asserted in the course of litigation. Unlike 21 C.F.R. § 808.1, which remains in effect and points away from any finding of preemption in this case, *see supra*, at 7-8, the agency's present view favoring preemption has been asserted only in legal briefs, and was not developed through notice-and-comment procedures that would have afforded Members of Congress, the States, and other interested persons an opportunity to participate. The FDA's failure to proceed by notice-and-comment procedures is in substantial tension with recent executive orders directed at correcting the tendency of agencies to overlook federalism principles when formulating views on preemption. *See, e.g.*, Executive Order No. 13,132, §§ 4, 6, 64 Fed. Reg. 43,255, 43,357-58 (Aug. 4, 1999) (requiring consultation with States and an opportunity for state and local officials to participate in rulemaking or adjudicatory proceedings with potentially preemptive consequences).

While in *Geier* this Court gave weight to an agency position on preemption expressed in legal briefs, this Court stressed that the agency had maintained its view "consistently over time." 529 U.S. at 883. That is not true in this case. Until 2004, the FDA considered its grant of a PMA *not* to preempt state product liability suits for injuries to patients or consumers caused by the device. *See* Brief for United States as Amicus Curiae in Opposition to Certiorari, *Kernats* (No. 96-1405). The FDA's prior approach reflected its longstanding view since enactment

of the MDA, also embodied in 21 C.F.R. § 808.1, that "the scope of preemption under [§ 360k] should be interpreted narrowly, with a presumption against preemption, ... particularly when the effect of preemption would be to override a state scheme offering greater consumer protection." Margaret Jane Porter, Chief Counsel of the Food & Drug Admin., *The Lohr Decision: FDA Perspective and Position*, 52 Food Drug L.J. 7, 7 (1997). The FDA has now turned its back on these principles with little explanation; indeed, the brief announcing the FDA's new position did not mention the presumption against preemption, or explain how the agency's recent conclusions could be reconciled with it.

A third reason to reject the FDA's current view of preemption in this case is that it is based on an anachronism. The FDA now seeks to characterize a grant of a PMA as prescribing specific requirements that establish both a floor and a ceiling as to the design and labeling of an approved device. Brief for United States as Amicus Curiae at 15, 29, *Horn*, 376 F.3d 163. But that was not the agency's view when it approved Medtronic's Evergreen Balloon Catheter for marketing in 1994 (or, for that matter, when the device was used in treating Charles Riegel in 1996). At that time, the FDA thought it was passing only on the question whether the Evergreen Catheter was minimally safe, and believed that state product liability suits would operate to provide strong and continuing incentives for Medtronic to seek to improve the device after marketing. Even if, contrary to the arguments above, the FDA could properly treat future PMA grants as preemptive, it would be rewriting history to characterize the 1994 PMA grant for the Evergreen Catheter as prescribing specific device requirements that establish both a safety floor and ceiling. That is simply not what the FDA thought it was doing in 1994.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

ANDREW M. CUOMO
Attorney General of the
State of New York
BARBARA D. UNDERWOOD*
Solicitor General
MICHELLE ARONOWITZ
Deputy Solicitor General
RICHARD DEARING
CECELIA CHANG
Assistant Solicitors General
120 Broadway, 25th Floor
New York, NY 10271
(212) 416-8020

Attorneys for Amici Curiae

* *Counsel of Record*

TERRY GODDARD
Attorney General
State of Arizona
1275 W. Washington
Phoenix, AZ 85007

DUSTIN MCDANIEL
Attorney General
State of Arkansas
323 Center Street, Suite 200
Little Rock, AR 72201

RICHARD BLUMENTHAL
Attorney General
State of Connecticut
55 Elm Street
Hartford, CT 06106

JOSEPH R. BIDEN, III
Attorney General
State of Delaware
Department of Justice
820 N. French Street
Wilmington, DE 19801

BILL MCCOLLUM
Attorney General
State of Florida
The Capitol, PL-01
Tallahassee, FL 32399

MARK J. BENNETT
Attorney General
State of Hawaii
425 Queen Street
Honolulu, HI 96813

LAWRENCE G. WASDEN
Attorney General
State of Idaho
P. O. Box 83720
Boise, ID 83720-0010

LISA MADIGAN
Attorney General
State of Illinois
100 West Randolph Street
Chicago, IL 60601

TOM MILLER
Attorney General
State of Iowa
1305 E. Walnut Street
Des Moines, IA 50319

PAUL J. MORRISON
Attorney General
State of Kansas
Memorial Hall, 2nd Floor
120 SW 10th Street
Topeka, KS 66612

DOUGLAS F. GANSLER
Attorney General
State of Maryland
200 Saint Paul Place
Baltimore, MD 21202

MARTHA COAKLEY
Attorney General,
Commonwealth of Mass.
One Ashburton Place
Boston, MA 02108

LORI SWANSON
Attorney General
State of Minnesota
102 State Capitol
75 Rev. Dr. Martin Luther King, Jr.
Boulevard
St. Paul, MN 55155

JIM HOOD
Attorney General
State of Mississippi
P.O. Box 220
Jackson, MS 39205

JEREMIAH W. (JAY) NIXON
Attorney General
State of Missouri
Supreme Court Building
207 West High Street
Jefferson City, MO 65101

MIKE MCGRATH
Attorney General
State of Montana
P.O. Box 201401
Helena, MT 59620-1401

CATHERINE CORTEZ MASTO
Attorney General
State of Nevada
100 North Carson Street
Carson City, NV 89701

GARY K. KING
Attorney General
State of New Mexico
P.O. Drawer 1508
Santa Fe, NM 87504

WAYNE STENEHJEM
Attorney General
State of North Dakota
600 E. Boulevard Avenue
Bismarck, ND 58505

MARC DANN
Attorney General
State of Ohio
30 E. Broad Street, 17th Fl.
Columbus, OH 43215

HARDY MYERS
Attorney General
State of Oregon
1162 Court Street N.E.
Salem, OR 97301

HENRY D. MCMASTER
Attorney General
State of South Carolina
Rembert C. Dennis Office Bldg.
P.O. Box 11549
Columbia, SC 29211-1549

ROBERT E. COOPER, JR.
Attorney General & Reporter
State of Tennessee
P.O. Box 20207
Nashville, TN 37202-0207

MARK L. SHURTLEFF
Attorney General
State of Utah
Utah State Capitol Complex
East Office Building, Suite 320
Salt Lake City, UT 84114

WILLIAM H. SORRELL
Attorney General
State of Vermont
109 State Street
Montpelier, VT 05609

ROB MCKENNA
Attorney General
State of Washington
1125 Washington Street S.E.
P.O. Box 40100
Seattle, WA 98504

DARRELL V. MCGRAW, JR.
Attorney General
State of West Virginia
State Capitol, Room 26-E
Charleston, WV 25305

J. B. VAN HOLLEN
Attorney General
State of Wisconsin
114 East, State Capitol
Madison, WI 53702

PATRICK J. CRANK
Attorney General
State of Wyoming
123 Capitol Avenue
Cheyenne, WY 82002

LINDA SINGER
Attorney General
The District of Columbia
One Judiciary Square
441 4th Street, N.W.
Suite 600 South
Washington, D.C. 20001